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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,895	03/14/2002	Mark Andrew Guthridge	3991/0K379US0	5422
7590 10/14/2004 DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			EXAMINER HOWARD, ZACHARY C	
			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,895

Applicant(s)

GUTHRIDGE ET AL.

Examiner

Zachary C Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a binding motif of a receptor, classified in class 530, subclass 350.
- II. Claims 15-19, drawn to a method of phosphorylating a binding motif of a receptor, comprising binding a triggering molecule to the receptor, classified in class 436, subclass 501.
- III. Claims 20 and 23, drawn to a method of binding a cytoplasmic protein to a receptor, comprising phosphorylating a binding motif to a receptor and subjecting the motif to a cytoplasmic protein, classified in class 436, subclass 501.
- IV. Claims 21-22 and 24-25, drawn to a method of activating cellular activities by regulating the activation of phosphorylation of a binding motif of a receptor followed by binding to a cytoplasmic protein, classified in class 435, subclass 375.
- V. Claims 26 and 27, drawn to a method of inhibiting cell survival by an antagonist which binds to the receptor motif, classified in class 435, subclass 375.
- VI. Claim 28, drawn to a method of inhibiting cell activation, classified in class 435, subclass 375.

- VII. Claim 29, drawn to a method of treating a cytokine mediated condition by regulating the activation of phosphorylation of a binding motif of a receptor, classification dependent upon compound administered.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the binding motif of Invention I, can be used in the process of Invention II, but can also be used in any of the processes of Inventions III-VII.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention II requires search and consideration of a method comprising binding a triggering molecule to the receptor to phosphorylate a binding motif, which is not required by any of the other Inventions. Invention III requires search and consideration of a method comprising phosphorylating a binding motif (by unspecified methods) followed by subjecting a cytoplasmic protein to the receptor, which are

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method steps and goals not required by any of the other Inventions. Invention IV requires search and consideration of a method of activating cellular activities by regulating the activation of phosphorylation of a binding motif of a receptor, which is not required by any of the other Inventions. Invention V requires search and consideration of a method of inhibiting cell survival, which is not required by any of the other Inventions. Invention VI requires search and consideration of a method of inhibiting cell activation, which is not required by any of the other Inventions. Cellular activation is a broad term that encompasses many cellular processes (e.g., proliferation, transformation, differentiation, etc...) other than those required for survival. Invention VII is drawn to methods of treating a cytokine-mediated condition by regulating phosphorylation of a binding motif of a receptor. This Invention requires search and consideration of methods of gene therapy or administration of a wide variety of antagonists to a subject with a disease, which are not required by any of the other Inventions.

Because these inventions are distinct for the reasons given above and the classification and/or search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

Further Restriction Within Groups I-VII

For whatever group is elected, further restriction within the elected group is required, as follows: one specific receptor binding motif selected from the list of 27

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different motifs in Claim 8. For the selected binding motif, the applicant should identify the corresponding SEQ ID number for that motif, each claim that reads on that motif, and one specific receptor encompassing that motif from the list of 22 in claim 7 (including the SEQ ID NO of the entire receptor, if applicable).

Although the classifications for the binding motifs from different receptors are overlapping, each binding motif represents a patentably distinct product that is capable of being made and used without the other motifs, has a different sequence that requires a separate sequence search, binds different cytoplasmic proteins, and is from different receptors that are involved in different cellular activities and pathways. Methods of using the binding motifs are also therefore patentably distinct.

Applicants are advised that this is not a species election.

Species election within Group IV

The invention listed as Group IV contains claims directed to the following patentably distinct species of cellular activities in the claimed invention: cell survival, proliferation, transformation, differentiation, mitogenesis, chemotaxis, motility, enhanced phagocytosis, bacterial killing, superoxide production and cytotoxicity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Paul F. Fehlner on 10/06/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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EILEEN B. O'HARA
PATENT EXAMINER